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10/551,780	11/29/2006	Motoharu Seiki	P28604	5607

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EXAMINER	
HALVORSON, MARK	
ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,780	SEIKI ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-13 and 16-33* is/are pending in the application.

4a) Of the above claim(s) *33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-13 and 16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7, 9-13, 16-33 are pending.

Claim 33 has been withdrawn.

Claims 1-7, 9-13, 16-32 are currently under examination.

35 USC § 103(a) rejections withdrawn

The rejection of claims 1-16, 18,19, 21-22, 24-32 under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (US Patent Application Publication 20020197210, published December 26, 2002, cited previously) in view of Kitagawa et al (J Urol, 1998, 160:1540-1545, Text, 1-8 in cited previously) is withdrawn in view of Applicants' amendments to claim 1.

The rejection of claims, 1 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (cited previously) in view of Kitagawa et al (cited previously) in further view of Cullis et al (US Patent No: 6,417,326, issued July 9, 2002) is withdrawn in view of Applicants' amendments to claim 1.

NEW REJECTIONS: Based on the Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-13, 16-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

There is no support in the specification as originally filed for the newly added limitation "herein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure". Table 2 only discloses DSPE-PEG-mal/DSPE-PEG(%) values of 0.5, 1, 5 10 and 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16, 18,19, 21-22, 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (US Patent Application Publication 20020197210, published December 26, 2002, cited previously) in view of Kitagawa et al (J Urol, 1998, 160:1540-1545, Text, 1-8 in cited previously) in further view of Zalipsky et al (US Patent No: 7,108,863, issued Sept 19, 2006, filed Mar 26, 2002).

The claims are drawn to lipid membrane structure containing an anti-membrane-type matrix metalloproteinase monoclonal antibody (anti-MT-MMP), wherein the lipid membrane structure contains a substance for binding the anti-MT-MMP to the lipid membrane structure and a blood retentive lipid derivative, wherein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure, wherein the monoclonal antibody is present in a lipid membrane, on a surface of lipid membrane, in a internal space of lipid membrane, in a lipid layer, and/or on a surface of lipid layer of the lipid membrane structure, wherein the monoclonal antibody binds to a membrane surface of the lipid membrane structure, wherein the monoclonal antibody consists of one or more kinds of monoclonal antibodies selected from an anti-MT1-MMP monoclonal antibody, an anti-MT2-MMP monoclonal antibody, an anti-MT3-MMP monoclonal antibody, an anti-MT4-MMP monoclonal antibody, an anti-MT5-MMP monoclonal antibody, and an anti-MT6-MMP monoclonal antibody, wherein the monoclonal antibody is a human monoclonal antibody or a mouse monoclonal antibody, wherein the monoclonal antibody is a Fab fragment, a F(ab').sub.2 fragment, or a Fab' fragment, wherein the substance for binding the monoclonal antibody to the lipid membrane structure is a lipid derivative that can react with mercapto group in the anti-MT-MMP monoclonal antibody, which contains a phospholipid and/or a phospholipid derivative as a component of the lipid membrane structure, wherein the phospholipid and/or the phospholipid derivative consists of one or more kinds of phospholipids and/or phospholipid derivatives selected from the group consisting of phosphatidylethanolamine, phosphatidylcholine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, cardiolipin, sphingomyelin, ceramide phosphorylethanolamine, ceramide phosphorylglycerol, ceramide phosphorylglycerol phosphate, 1,2-dimyristoyl-1,2-deoxyphosphatidylcholine, plasmalogen and phosphatidic acid, which further contains a sterol as a component of the lipid membrane structure, wherein the sterol is cholesterol and/or cholestanol, which contains a temperature-sensitive lipid derivative as a component in the lipid membrane structure, which contains a pH-sensitive lipid derivative as a component of the lipid membrane

structure, which reacts with a membrane-type matrix metalloproteinase on a tumor cell membrane, wherein the tumor cell is an MT-MMP expressing cell, wherein the tumor cell is a cell of fibrosarcoma, squamous carcinoma, neuroblastoma, breast carcinoma, gastric cancer, hepatoma, bladder cancer, thyroid tumor, urinary tract epithelial cancer, glioblastoma, acute myeloid leukemia, pancreatic duct cancer or prostate cancer, which reacts with a membrane-type matrix metalloproteinase of a neoplastic vessel, wherein the lipid membrane structure is in the form of micelle, emulsion, liposome or a mixture, which is in a form of dispersion in an aqueous solvent, a lyophilized form, a spray-dried form or a frozen form, a pharmaceutical composition comprising the lipid membrane structure according to claim 1 and a medicinally active ingredient and/or a gene, wherein the medicinally active ingredient and/or gene is present in a lipid membrane, on a surface of lipid membrane, in an internal space of lipid membrane, in a lipid layer and/or on a surface of lipid layer of the lipid membrane structure, wherein the pharmaceutical composition is in a form of a dispersion in an aqueous solvent, a lyophilized form, a spray-dried form, or a frozen form.

Bednarski et al disclose a therapeutic agent comprising a lipid construct, a targeting entity and a therapeutic or treatment entity, (claim 1, paragraph 46) wherein the lipid construct is a liposome, (paragraphs 51-55) the targeting entity is an antibody including monoclonal antibodies and antibody fragments and other antibody-derived molecules which retain specific binding, such as Fab, F(ab')2, Fv, and scFv derived from antibodies) (paragraph 76-83), which target entities such as the matrix metalloproteases. (claim 15). The therapeutic agent may be used to treat cancer (paragraph 91) The antibody may be attached to the lipid molecules of the liposome through disulfide bonds. (paragraphs 60). The liposome comprise phospholipids, including phosphatidylcholine and phosphatidylethanolamine (paragraph 51), cholesterol (paragraph 53) and stabilizing agents, such as polyethylene glycol, which increase the half-life of the liposome in the circulation. (paragraphs 65-68). The phospholipids of the liposomes are temperature and pH sensitive. Bednarski also discloses therapeutic entities including doxorubicin or other chemotherapeutic agents. (paragraph 48) which may be encapsulated by the liposome or may be associated on

the surface of the liposome (paragraph 46). The composition comprising the liposomes can also include other components such as a pharmaceutically acceptable excipients, such as water, saline, Ringer's solution, dextrose solution, mannitol, Hank's solution, and other aqueous physiologically balanced salt solutions. (paragraph 88).

Bednarski et al does not disclose a monoclonal antibody consists of one or more kinds of monoclonal antibodies selected from an anti-MT1-MMP monoclonal antibody, an anti-MT2-MMP monoclonal antibody, an anti-MT3-MMP monoclonal antibody, an anti-MT4-MMP monoclonal antibody, an anti-MT5-MMP monoclonal antibody, and an anti-MT6-MMP monoclonal antibody that that targets tumor cells including urinary tract epithelial cancer and reacts with membrane-type matrix metalloproteinase of a neoplastic vessel, wherein the tumor cell is a cell of fibrosarcoma, squamous carcinoma, neuroblastoma, breast carcinoma, gastric cancer, hepatoma, bladder cancer, thyroid tumor, urinary tract epithelial cancer, glioblastoma, acute myeloid leukemia, pancreatic duct cancer or prostate cancer, which reacts with a membrane-type matrix metalloproteinase of a neoplastic vessel

Kitagawa et al discloses an anti-MT1-MMP monoclonal antibody which bound MT1-MMP on tissue specimens of urothelial carcinoma cells. (page 4, 1st paragraph; page 5, 2nd paragraph, Figure 5). The tissue specimens would include neoplastic vessels.

One of ordinary skill in the art would apply Kitagawa et al's monoclonal antibody to MT1-MMP to Bednarski et al's therapeutic agent comprising an immunoliposome because Bednarski et al claims target entities such as the matrix metalloproteases which include the specie MT1-MMP. Furthermore Kitagawa et al disclose that MT1-MMP is expressed on carcinoma cells which would make MT1-MMP a suitable target for Bednarski et als' immunoliposme. It would have been prima facie obvious to combine Bednarski et al's therapeutic agent comprising an immunoliposome with Kitagawa et al's monoclonal antibody to MT1-MMP to make an immunoliposme that recognized MT1-MMP to target urothelial carcinoma cells expressing MT1-MMP.

Further, neither Bednarski et al nor Kitagawa et al disclose that the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5

and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure.

Zaplipsky et al disclose a DSPE-PEG-mal to DSPE-PEG of 0.5 % while optimizing the cytotoxitiy of immunoliposomes to CD19+ cells. (Table 1).
One of ordinary skill in the art would have been motivated to apply Zaplipsky et al's ratio of DSPE-PEG-mal to DSPE-PEG to Bednarski et al and Kitagawa et al's immunoliposme that recognized MT1-MMP to optimize the delivery of the immunoliposome to the target urothelial carcinoma cells. It would have been prima facie obvious to combine Bednarski et al and Kitagawa et al's immunoliposme to Zaplipsky et al's ratio of DSPE-PEG-mal to DSPE-PEG to optimize delivery of immunoliposmes that recognized MT1-MMP to maximize cytotoxicity towards urothelial carcinoma cells.

Claims, 1 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (cited previously) in view of Kitagawa et al (cited previously) in further view of Cullis et al (US Patent No: 6,417,326, issued July 9, 2002, cited previously), and Zalipsky et al (US Patent No: 7,108,863, issued Sept 19, 2006, filed Mar 26, 2002, cited previously).

The claims are drawn to lipid membrane structure containing an anti-membrane-type matrix metalloproteinase monoclonal antibody (anti-MT-MMP), wherein the lipid membrane structure contains a substance for binding the anti-MT-MMP to the lipid membrane structure and a blood retentive lipid derivative, wherein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure, wherein the temperature-sensitive lipid derivative is dipalmitoylphosphatidylcholine, pH-sensitive lipid derivative is dioleoylphosphatidylethanolamine.

Bednarski et al and Kitagawa have been described supra.

Neither Bednarski et al nor Kitagawa disclose the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine.

Cullis et al disclose liposomes comprising dipalmitoylphosphatidylcholine (column 10, lines 39-40) and dioleoylphosphatidylethanolamine. (column 14 ,lines 61-65).

One of ordinary skill in the art would have been motivated to apply Cullis et al's disclosure of the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine to Bednarski et al and Kitagawa et al's immunoliposme because Bednarski et al disclosed that the materials which may be utilized in preparing the liposomes include any of the materials known in the art suitable in liposome construction. (paragraph 53). Bednarski et al's also disclosed that such materials include lipids with head groups including phosphatidylcholine and phosphatidylethanolamine. (Id). It would have been prima facie obvious to combine Bednarski et al and Kitagawa et al's immunoliposme with Cullis et al's disclosure of the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine to make an immunoliposme including the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine which are lipids that include the head groups phosphatidylcholine and phosphatidylethanolamine, respectively.

Further, neither Bednarski et al, Kitagawa et al nor Cullis et al disclose that the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure.

Zaplipsky et al disclose a DSPE-PEG-mal to DSPE-PEG of 0.5 % while optimizing the cytotoxitiy of immunoliposomes to CD19+ cells. (Table 1).
One of ordinary skill in the art would have been motivated to apply Zaplipsky et al's ratio of DSPE-PEG-mal to DSPE-PEG to Bednarski et al, Kitagawa et al and Cullis et al's immunoliposme that recognized MT1-MMP to optimize the delivery of the immunoliposome to the target urothelial carcinoma cells. It would have been prima facie obvious to combine Bednarski et al, Kitagawa et al and Cullis et al's immunoliposme to Zaplipsky et al's ratio of DSPE-PEG-mal to DSPE-PEG to optimize delivery of immunoliposmes that recognized MT1-MMP to maximize cytotoxicity towards urothelial carcinoma cells.

Claims 1 and 14 -17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (, cited previously) in view of Kitagawa et al (cited previously) in further view of Slater et al (US Patent No: 6,355, 268, issued March 12, 2002, cited previously) and Zalipsky et al (US Patent No: 7,108,863, issued Sept 19, 2006, filed Mar 26, 2002, cited previously).

The claims are drawn to lipid membrane structure containing an anti-membrane-type matrix metalloproteinase monoclonal antibody (anti-MT-MMP), wherein the lipid membrane structure contains a substance for binding the anti-MT-MMP to the lipid membrane structure and a blood retentive lipid derivative, wherein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure, comprising a polyethylene glycol-lipid derivative consisting of one or more kinds of polyethylene glycol-lipid derivatives selected from the group consisting of N-{carbonyl-methoxypolyethylene glycol-2000}-1,2-dipalmitoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-5000}-1,2-dipaimitoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-750}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-2000}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine and N-{carbonyl-methoxypolyethylene glycol-5000}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine.

Bednarski et al and Kitagawa et al have been described supra.

Neither Bednarski et al nor Kitagawa disclose the polyethylene glycol-lipid derivatives selected from the group consisting of N-{carbonyl-methoxypolyethylene glycol-2000}-1,2-dipalmitoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-5000}-1,2-dipaimitoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-750}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-2000}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine and N-{carbonyl-methoxypolyethylene glycol-5000}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine.

Slater et al disclose liposomes comprising N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine. (column 23, lines 14-18).

One of ordinary skill in the art would have been motivated to apply Slater et al's disclosure of the polyethylene glycol-lipid derivative, N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine to Bednarski et al and Kitagawa et al's immunoliposme because Bednarski et al disclosed that the materials which may be utilized in preparing the liposomes include any of the materials known in the art suitable in liposome construction and proposes polyethylene glycol as an exemplary stabilizing polymer (paragraph 68). It would have been prima facie obvious to combine Bednarski et al and Kitagawa et al's immunoliposme with Slater et al's disclosure of the polyethylene glycol-lipid derivative, N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine to make an immunoliposme including the stabilizing agent N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine.

Further,neither Bednarski et al, Kitagawa et al nor Slater et al disclose that the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure.

Zaplipsky et al disclose a DSPE-PEG-mal to DSPE-PEG of 0.5 % while optimizing the cytotoxitiy of immunoliposomes to CD19+ cells. (Table 1).

One of ordinary skill in the art would have been motivated to apply Zaplipsky et al's ratio of DSPE-PEG-mal to DSPE-PEG to Bednarski et al, Kitagawa et al and Slater et al's immunoliposme that recognized MT1-MMP to optimize the delivery of the immunoliposome to the target urothelial carcinoma cells. It would have been prima facie obvious to combine Bednarski et al, Kitagawa et al and Slater et al's immunoliposme to Zaplipsky et al's ratio of DSPE-PEG-mal to DSPE-PEG to optimize delivery of immunoliposmes that recognized MT1-MMP to maximize cytotoxicity towards urothelial carcinoma cells.

Summary

Claims 1-7, 9-13, 16-32 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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